

### **REMARKS**

Claims 2, 3, 5, 6, 9, and 11-26 are pending in the application and are at issue.

Claims 9 and 17 have been amended with respect to the amount of hydric solvent in the composition , now reciting a minimum of 20% and 10%, by weight, respectively. The amendment to claim 17 is supported by original claim 16 and the specification at page 12, lines 18-21. The amendment to claim 9 is supported by the specification at page 25, wherein the table discloses a dipropylene glycol range of 20% - 35%, by weight.

Claim 9 also has been amended to recite that the compound consists of dipropylene glycol, therefore excluding the benzyl alcohol of claim 17. Claim 16 has been amended to recite dipropylene glycol as the hydric solvent.

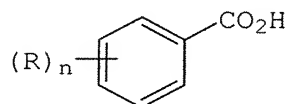
The claims also have been amended to rewrite claim 22 as an independent claim, and to overcome a rejection under 35 U.S.C. §112, second paragraph.

### **THE INVENTION**

The present invention is directed to a method of reducing a bacteria and/or virus population on a surface by contacting the surface with an antimicrobial composition. After 30 seconds of contact with the composition, the surface demonstrates a log reduction of at least 3 against *S. aureus* and/or *E. coli* (independent claim 17 and claim 18). The method also demonstrates antiviral activity (claims 19, 20, and 22-24). The surface can be animate (claim 21) or inanimate.

The composition in the claimed methods comprise (claim 17 and claim 22):

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol, benzyl alcohol, or a mixture thereof;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,  
wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

Claims 2, 3, 5, 6, 9, 11-16, 25, and 26 recite more specific embodiments of the composition.

Some important features of the claimed composition are (a) the aromatic carboxylic acid is the *sole* antimicrobial agent in the composition, (b) the composition contains 0% to 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant, *and* (c) the composition contains a hydric solvent comprising dipropylene glycol, benzyl alcohol, or a mixture thereof. In claims 9 and 16, dipropylene glycol is the sole hydric solvent. As discussed below, the claimed compositions demonstrate unexpected results for a composition lacking a second antimicrobial agent and/or a surfactant.

Applicants particularly direct the examiner's attention to the examples in the specification. In particular, Examples 1-3 show that pH is important to achieve efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic acid alone, i.e., in the absence of a hydric solvent, is not efficacious (Ex. 3). By "not

efficacious", it is meant that the claimed log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact was not achieved.

Example 4 in the specification illustrates that a minimum amount of hydric solvent is required to achieve the claimed log reduction of at least 3. As stated in the specification at page 25:

"It is envisioned that a minimum amount of hydric solvent is needed in a composition to provide an AEI of at least 3, and this minimum amount is related to the identity of the hydric solvent, solution pH, and aromatic carboxylic acid concentration. The minimum amount of hydric solvent can be readily determined for any composition by the test criteria described in this example."

Applicants therefore have amended the claims to more clearly recite the minimum amount of hydric solvent to provide a claimed log reduction of at least 3 after 30 seconds of contact with the claimed composition.

#### REJECTION UNDER 35 U.S.C. §112

Claims 11 and 12 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to further limit these dependent claims. In response, applicants have amended claims 11 and 12 as suggested by the examiner. Therefore, it is submitted that this rejection of claims 11 and 12 has been overcome and should be withdrawn. Applicants similarly have amended claim 26 to improve the form of claim 26.

#### REJECTION UNDER 35 U.S.C. §103

Claims 2, 3, 5, 6, 9, and 11-26 stand rejected under 35 U.S.C. §103 as being obvious over Beerse et al. U.S. Patent No. 6,294,186 ('186). The examiner contends that the '186 patent renders the claimed methods obvious because the cited reference teaches compositions containing the same ingredients as the claimed compositions, and therefore are expected to provide similar characteristics. For the reasons set forth below, it is submitted that this rejection is in error and should be withdrawn.

THE CITED '186 PATENT

The '186 patent primarily teaches an antimicrobial composition containing a benzoic acid analog *and* a metal salt ('186 patent abstract). See '186 patent, column 3, lines 32-48. The '186 patent further teaches, explicitly, that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states, at column 7, lines 60-65:

"Without being limited by theory, it is believed that in the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide a synergistic immediate and residual anti-viral and antibacterial efficacy to surfaces to which such compositions are applied."

The '186 patent also contains 42 examples. Of these examples, 41 contain a metal salt as an antimicrobial agent *in addition to* the aromatic carboxylic acid.

The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. See '186 patent, column 47, lines 18-54. The '186 patent contains one example (Example 21) that is free of a metal salt. However, the composition of this example also contains a total of 10 wt% of surfactants *and* 1.50% para-chloro-meta-xyleneol (a second antimicrobial agent). The definition of dermatologically effective carriers in the '186 patent includes surfactants of the type disclosed in Example 21. See '186 patent, column 8, line 49 through column 9, line 3.

With respect to a hydric solvent, the '186 patent, at column 9, lines 33-54, discloses that a carrier for the disclosed composition can be an alcohol. The alcohol is broadly disclosed as monohydric and dihydric alcohols. Specific disclosed alcohols are monohydric alcohols, e.g., methanol. The sole disclosure of a dihydric alcohol, i.e., dipropylene glycol, is in Examples 16-18. In these examples, the amount of dipropylene glycol is 8%, by weight, which amount if present in a claimed composition, is insufficient to provide a claimed log reduction of at least 3. It also must be noted that Examples 16-18 of the '186 patent each include a metal salt, which is *excluded* from the present claims.

The other '186 patent examples referred to by the examiner, i.e., Examples 4, 12, 14, and 15 are free of a hydric solvent and contain a metal salt (which is excluded from the present claims).

#### NONOBVIOUS DIFFERENCES BETWEEN THE CITED '186 PATENT AND THE PRESENT CLAIMS

As stated above, the presently claimed method utilizes a composition that (a) contains an aromatic carboxylic acid as the *sole* antimicrobial agent, (b) contains an amount hydric solvent to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* after 30 seconds contact, and (c) contains 0% to 0.2%, by weight, of a surfactant. The '186 patent fails to teach or suggest a composition having this combination of features.

The '186 patent explicitly teaches that the metal salt is an essential ingredient in one embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims *exclude* the presence of a metal salt that is taught as essential in the '186 patent. In particular, the claims clearly recite that the aromatic carboxylic acid is the *sole* antimicrobial agent in the composition.

In the second embodiment disclosed in the '186 patent, a metal salt is absent from a composition containing a benzoic acid analog and a dermatologically acceptable carrier. However, the sole example of this embodiment, i.e., Example 21, differs in *three* substantial ways from the present composition. First, although the composition of Example 21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50%, by weight, of the phenolic antimicrobial para-chloro-meta-xlenol (PCMX). See the '186 patent, column 20, line 34 through column 22, line 37, and especially column 21, lines 59-60. This phenolic antimicrobial agent is excluded from the present claims, i.e., it is *not* an aromatic carboxylic acid.

Second, a major carrier exemplified in the '186 patent in connection with this embodiment is a high (10 wt%) amount of surfactant (see '186 patent, Example 21). In contrast, the present claims recite a composition that contains 0% to about 0.2%, by weight, of a composition. Third, Example 21 of the '186 patent also is free of a hydric solvent, which

is a presently claimed ingredient in an amount of about 10% to about 40%, by weight, of the composition, and which is required to provide a composition capable of providing an at least log 3 reduction in *S. aureus* and/or *E. coli* after 30 seconds of contact. The sole example of the '186 patent that is free of a metal salt therefore is completely different from a composition recited in the present claims.

The '186 patent also discloses that the carrier can be an alcohol solution, i.e., monohydric and/or dihydric alcohols. The preferred alcohols are monohydric C2-C18 alcohols, and the only specifically named alcohols are ethanol, isopropanol, n-propanol, butanol, and mixtures thereof. In contrast, the present claims recite dipropylene glycol, benzyl alcohol, or mixtures thereof as components of the hydric solvent. Claim 9 is limited to dipropylene glycol ethanol as the hydric solvent. Although the '186 patent discloses dipropylene glycol in Examples 16-18, these examples each include (a) a metal salt and (b) the dipropylene glycol is present in too low an amount to provide an efficacious composition, as claimed, in the absence of a metal salt.

In contrast to the teachings of the '186 patent, the present claims recite a composition wherein an aromatic carboxylic acid is the *sole* antimicrobial agent in the composition *and* the composition contains 0% to about 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant *and* the composition contains an amount of hydric solvent to achieve a log reduction of at least 3 against *S. aureus* and *E. coli* after 30 seconds contact.

At pages 5-8 of the Office Action, the examiner provides responses to applicants' previous arguments, and many of the statements show a definite hindsight reconstruction of applicants' invention. In particular, the examiner has selected isolated teachings (i.e., ingredients or lack of ingredients) from different examples of the '186 patent to reconstruct applicants' claimed composition while *neglecting* other features present in the same example relied upon by the examiner.

For example, the examiner states at page 6:

"Applicant argues that Beerse et al teach that the addition of a metal-acid complex is "found to provide a synergistic immediate and residual anti-viral and antibacterial efficacy to surfaces to which such

compositions are applied" and therefore suggest that the metal-acid, in addition to the aromatic acid compound, acts as an additional anti-microbial agent.

The examiner contends that applicant's claims are bound by the transitional phrase of "comprising which permits the inclusion of additional components not specified in the claim. Moreover, as stated by applicant", Beerse et al do not require metal-salts in all of the embodiments and specifically suggest that the embodiments free of metal salts are effective in provide residual anti-viral efficacy (col. 47, lines 18-55) Therefore, Beerse et al do not require a metal-salt component as suggested by applicant, and further applicant's claims permit the use of additional ingredients not specified."

First, applicants do not argue that the benzoic acid analyze and metal salt complex provide synergistic results. This is explicitly taught by the '186 patent, and the language used by the examiner is a quote from the '186 patent (see '186 patent, column 7, lines 60-65).

With respect to the contention that the term "comprising" allows additional components to be included in the composition, it must be pointed out that the claims specifically are limited to the aromatic carboxylic acid being the sole antimicrobial agent. Additional antimicrobial agents are excluded.

With respect to the examiner's comment that the '186 patent does not require a metal salt component, the only example free of a metal salt has both (a) 1.5 wt % of a second phenolic antimicrobial agent and (b) 10 wt % of a surfactant. Although the '186 patent at column 47, lines 18-54 suggests use of a benzoic acid analog in the absence of a metal salt, the reference *explicitly* teaches that a second antimicrobial agent is present to add to the efficacy of the composition. Therefore, the phenolic antimicrobial agent present in Example 21 provides a boost in antimicrobial activity because the metal salt is absent. A presently claimed composition is *free* of both a second antimicrobial agent and a surfactant.

At page 6 of the Office Action, the examiner further states:

"Applicant argues that Beerse et al fail to suggest a surfactant having 0 to 0.2%; and 5 to 50% by weight of a hydric solvent.

The examiner respectfully disagrees and directs applicant's attention to column 27, lines 55-60, which teaches less than 10% by weight of surfactants are needed. Moreover, as stated above, examples 13 and 17 do not disclose a surfactant. With respect to the hydric solvent, example 17 states 8% by weight of dipropylene glycol.

Applicant argues that example 21 does not comprise a metal-salt but also does suggest high levels of surfactants."

First, the '186 patent at column 27, lines 56-59 actually states that *co-surfactants* are present at less than 10% by weight. Prior to this limited disclosure, the '186 patent discloses innumerable surfactants at columns 22-27, but fails to disclose any specific amount of amount of surfactant. The disclosure relating to co-surfactants relates to *additional* surfactants that *also* can be included. Accordingly, the examiner's reliance on column 27, lines 56-59 is misplaced. Moreover, the '186 patent fails to disclose a composition essentially (a) free of a surfactant, (b) free of a metal salt, *and* (c) free of a second antimicrobial agent. The examiner's reasoning is an example of hindsight reconstruction wherein an isolated statement is used to support a rejection without a consideration either of the claimed invention as a whole or the *complete* teachings of the reference.

With respect to Examples 13 and 17, they may not contain a surfactant, but they *do* contain a metal salt, i.e., FeCl<sub>3</sub> and CuCl<sub>2</sub>/ZnCl<sub>2</sub>, respectively. Again, the examiner is looking at an isolated ingredient, or lack thereof, to support a nonobviousness rationale, without considering the claimed invention as a whole or a complete teaching of the reference, in order to reconstruct the claims through hindsight. With further respect to claim 17, the amount of dipropylene glycol is present in too low an amount to provide a claimed log reduction of at least 3 against *S. aureus* and/or *E. coli* after 30 seconds contact in the absence of a metal salt.

In addition, Example 21 does not "suggest" high levels of surfactants. Example 21 *explicitly teaches* 5.0% ammonium lauryl sulfate and 5.0% ammonium laureth-3 sulfate, or 10.0% total surfactant, by weight. This is 50 times the claimed maximum of surfactant.



At page 7 of the Office Action, the examiner states:

"The examiner contends that a reference does not need to teach each of the components in an example to be indicative of obviousness. The general teaching of Beerse et al states that metal –salt complex is not require [sic] to perform as suggested (col. 47, lines 18-55). Moreover, Beerse et al teach several embodiments that do not require surfactants (see examples 4, 12, 14-15, 16-18).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989)."

The examiner appears to be saying that as long as individual ingredients of a composition can be found in a reference, then a claim can be found obvious. In looking at different embodiments of the '186 patent, the examiner is focusing on individual ingredients that may or may not be present, then adding the various ingredients together or deleting ingredients, to arrive at a conclusion of obviousness.

However, the examiner is "cherry picking" these individual ingredients without considering either the entire teaching of the embodiments in the '186 patent or the claimed invention as a whole. The sole explicit teaching of a composition that is free of a metal salt in the '186 patent (Example 21) contains 10 wt % of a surfactant and 1.5 wt. % of a second antimicrobial agent, *both* of which are excluded from the present claims. The examples relied upon by the examiner all are free of a surfactant, but all *contain* a metal salt, which is excluded from the present claims.

In general, the examiner's reasoning also is inconsistent. To support exclusion of a metal salt, the examiner relies upon the limited general teachings of the '186 patent at column 47, lines 18-55, but neglects the specific teaching on Example 21. However, to support exclusion of a surfactant the examiner neglects the extensive general teachings at *columns* 22-27 of the '186 patent to include a surfactant, but relies upon specific examples to exclude a surfactant. Overall, it is submitted that the '186 patent would *not* have *reasonably* suggested to a person skilled in the art to exclude a second antimicrobial agent *and* exclude

surfactants *and* exclude a metal salt *and* include a sufficient amount of hydric solvent to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* after 30 seconds contact.

The examiner contends that testing against comparative examples is necessary to support patentability. However, applicants are not claiming an improvement over the '186 patent, but are claiming a method using an entirely different composition. The '186 patent contains no objective evidence of efficacy, but merely a definition of "residual antibacterial activity" at column 4, lines 22-39, and "Analytical Methods" at columns 44-46. However, even assuming *arguendo* that the '186 patent compositions are efficacious, comparing the present compositions to the '186 patent composition would serve little purpose. The compositions of the '186 patent arguably would be shown as efficacious, and applicants already have shown that the claimed compositions are efficacious.

The present invention is a discovery that, contrary to the '186 patent, the claimed composition is efficacious in the *absence* of a metal salt, in the *absence* of a surfactant, and in the *absence* of any other second antimicrobial agent. The '186 patent fails to lead a person skilled in the art to make these multiple jumps in reasoning, and *then* include a sufficient amount of a claimed hydric solvent to provide the claimed log reduction of *S. aureus* and/or *E. coli* after 30 seconds contact.

More particularly, the present invention is demonstrated in the examples, wherein it is shown that an aromatic carboxylic acid or a hydric solvent *alone* does not provide a high antimicrobial efficacy, as claimed. Both the aromatic carboxylic acid and hydric solvent are needed to achieve a high antimicrobial efficacy, and a sufficient amount of the hydric solvent also is needed (see specification, Example 4).

In effect, applicants have provided comparative testing to the closest prior art. If one takes a composition from the '186 patent, and following the examiner's strained reasoning, then excludes the metal salt *and* a surfactant *and* any other second antimicrobial agent, the resulting composition would be those tested in Examples 1, 3, and 4. These examples shown that simply excluding one or more of these components does not provide a composition having the claimed efficacy. What is needed is a combination of aromatic carboxylic acid and a sufficient amount of hydric solvent, as claimed. It was the applicants

that made the inventive discovery of including a hydric solvent in the claimed amounts to provide a highly efficacious composition for use in the claimed method. This discovery is neither taught nor suggested in the '186 patent.

The presently claimed invention clearly exhibits unexpected results, even when the essential metal salt of the '186 patent is omitted. In particular, the present examples show an unexpectedly high antimicrobial efficacy when both an aromatic carboxylic *and* a claimed hydric solvent are present (see Examples 1, 4, 7, and 9). Comparative Examples 2 and 3 show that both the aromatic carboxylic acid *and* hydric solvent are needed to achieve a high antimicrobial efficacy.

The differences between present claims and the '186 patent would not have been obvious to a person skilled in the art under 35 U.S.C. §103. In fact, the '186 patent fails to make the present claims *prima facie* obvious. Simply put, the '186 patent provides no apparent reason to modify the '186 patent as suggested by the examiner with any reasonable expectation of providing an efficacious antibacterial method. The '186 patent stresses the necessity of including a metal salt or other second antimicrobial agent in the composition in order to achieve an enhanced antimicrobial action. For example, the '186 patent includes 42 examples, of which 41 contain a metal salt as an antimicrobial component. The sole example in the '186 patent omitting a metal salt, i.e., Example 21, contains a high percentage of anionic surfactant *and* is lacking a hydric solvent *and* contains a second antimicrobial agent. The '186 patent fails to teach or suggest a composition that (a) omits a metal salt and other additional antimicrobial agents, *and* (b) is essentially free of a surfactant, *and* (c) includes a hydric solvent, as presently claimed. From the teachings of the '186 patent, a person skilled in the art would not have been motivated to omit a metal salt *and* omit a surfactant *and* include a claimed hydric solvent with any reasonable expectation of providing a useful antimicrobial composition.

In summary, persons skilled in the art simply would not be motivated make the several jumps in reasoning needed to arrive at the presently claimed invention after reading the '186 patent. Therefore, in view of the substantial differences between the '186 patent and the present claims, it is submitted that the rejection of the pending claims as being obvious over the '186 patent under 35 U.S.C. §103 should be withdrawn.

REJECTION UNDER 35 U.S.C. §103

Claims 2, 3, 5, 6, 9, and 11-19, 22, and 25-26 stand rejected under 35 U.S.C. §103 as being obvious over the Hei et al. U.S. Patent Publication No. 2002/0168422 ('422 publication). It is submitted that this rejection is in error and should be withdrawn.

THE CITED '422 PUBLICATION

The '422 publication is directed to a two solvent antimicrobial composition, wherein a second solvent is insoluble or sparingly soluble in a diluting solvent. The two solvent composition can be used alone or in conjunction with an optional cosolvent, surfactant, or antimicrobial agent ('422 publication, [0010] and [0013]). The compositions are designed for use on inanimate surfaces.

The '422 publication discloses that water is a preferred diluting solvent, but a variety of diluting solvents, including perchloroethylene, organic and inorganic acids, peroxides, silicone oils, etc., are disclosed at [0086]. The second antimicrobial solvent is defined at [0089]–[0110]. Paragraph [0091] states that "[A]ny of a variety of solvents can be useful as antimicrobial solvents," then lists an estimated 50 to 100 solvents, including benzyl alcohol and six other preferred solvents. The '422 publication is particularly directed to using a diester dicarboxylate as the second solvent ([0094]–[0110]).

With respect to antimicrobial agents, the '422 publication disclose a myriad of agents at paragraphs [0111]–[0141]. Included in this extensive list is carboxylic acids and esters, iodo-compounds, sulfonic acids, oxygen compounds, peroxides, phenolics, for example. The '422 publication is especially directed to peroxycarboxylic acids and esters as antimicrobial agents ([0119]–[0141]).

The '422 publication also discloses cosolvents at [0142]–[0147]. Contrary to the examiner's assertion, the '422 publication does *not* disclose dipropylene glycol at [0144]–[0147]. In [0144], the reference discloses the methyl, propyl, and tert-butyl *ethers* of dipropylene glycol, but not dipropylene glycol itself. The disclosed ethers are different compounds from dipropylene glycol and have different properties.

The '422 publication further discloses that the compositions can contain a variety of other ingredients, including surfactants (see [0148]).

The numerous examples of the '422 publication show that the disclosure is particularly directed to the art of antimicrobial compositions containing a peroxycarboxylic acid as the antimicrobial agent and a diester dicarboxylate as the second solvent. With respect to the benzyl alcohol disclosure relied upon by the examiner, data in Table I shows that benzyl alcohol is used *with* a peracid (Run Nos. 1-10 and 1-11) and with a surfactant (Run No. 1-10).

Table II contains data on benzyl alcohol-containing compositions (0% to 5%) together with surfactants, ethanol, a peracid, solvents, glycerin, a diester blend, or NaOCl. The amounts of benzyl alcohol are low, and alone (with a low or high amount of surfactant or ethanol) are ineffectual (see Run Nos. 2-1, 2-2, 2-7, and 2-8). Effective compositions contain a peracid.

Table III, Run 3-14, shows the antifungal effect of 5% benzyl alcohol in water. The composition does not contain an aromatic carboxylic acid. Benzyl alcohol also is used in numerous other examples, but typically together with a peracid. When used alone, the benzyl alcohol did not perform well against bacteria (see Run. Nos. 5-6, 5-8, 5-10, 5-18, 10-4, 11-5, for example). Run 12-3 utilizes benzoic acid, but in the presence of a peracid. No example or test disclosed in the '422 publication utilized an aromatic carboxylic acid as the sole antimicrobial agent. Dipropylene glycol is not disclosed in the '422 publication.

#### NONOBVIOUS DIFFERENCES BETWEEN THE '422 PUBLICATION AND THE PRESENT CLAIMS

The Patent Office "has the burden under §103 to establish a prima facie case of obviousness." *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); MPEP §2141 (8<sup>th</sup> Ed., Rev. 6, Sept. 2007) ("The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness."). The Supreme Court recently identified a number of rationales that may be used to support a conclusion of obviousness, consistent with the framework set forth in its decision in *Graham v. John Deere Co.* See *KSR Int'l Co. v. Teleflex Inc.*, 127

S.Ct. 1727, 1739-40 (2007). These and other representative rationales are described at MPEP §2143 (8<sup>th</sup> Ed., Rev. 6, Sept. 2007). Regardless of the supporting rationale, however, the Patent Office must clearly articulate *facts* and *reasons* why the claimed invention "as a whole" would have been obvious to a hypothetical person having ordinary skill in the art at least as of the claimed invention's effective filing date. The Court specifically stated:

"Often, it will be necessary...to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**."; and

"Therefore in formulating a rejection under 35 U.S.C. §103 (a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the matter claimed."

See *KSR Int'l*, 127 S.Ct. at 1741 (citing with approval *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")); *see also* MPEP §2143 ("The key to supporting any rejection under 35 USC §103 is the clear articulation of reason(s) why the claimed invention would have been obvious.").

The examiner has not clearly articulated facts and reasons why the claimed invention "as a whole" would have been obvious over the '422 publication to a hypothetical person having ordinary skill in the art. The action refers to various paragraphs in the '422 publication, then states in a conclusory fashion that the present claims would have been obvious. The examiner provided no rationale as to why a person skilled in the art after reading the '422 publication would make numerous jumps in reasoning related to modifying the reference in a manner that would lead to the claimed invention.

In particular, the examiner relies upon a series of definitions and a broad range of ingredients and weight percentages disclosed in the '422 publication, then summarily states a person skilled in the art somehow would arrive at the specifically claimed invention. Like

the rejection based on the '186 patent, this rejection appears to be a hindsight reconstruction of the claims. The examiner relies upon the reference because it discloses benzyl alcohol, water, and salicylic acid. Contrary to the examiner's assertion, the reference does not teach dipropylene glycol. However, the '422 publication resembles a chemical dictionary by reciting a vast number of antimicrobial solvents and antimicrobial agents, and extremely wide ranges for each ingredient, e.g., 0.001% to 95%. Contrary to the examiner's assertion, the reference does not teach dipropylene glycol or any component's percentage with any degree of specificity to render the claimed weight percentages obvious. Based on the very broad '422 publication disclosure, the examiner's rationale cannot be obvious-to-try because of the sheer number of permutations of ingredients and percentages disclosed in the '422 publication.

The '422 publication contains numerous examples utilizing benzyl alcohol, many of which show that benzyl alcohol is not efficacious. Typically, benzyl alcohol is used in the '422 publication together with a peracid antibacterial agent. Benzyl alcohol is used alone in many examples, but at a weight percent below the claimed minimum. One example contains 10 wt% benzyl alcohol, but is not efficacious against bacteria (see Run 5-6). The '422 publication absolutely fails to disclose the other claimed hydric solvent, i.e., dipropylene glycol (see claim 9).

In the absence of dipropylene glycol, the '422 publication also fails to specifically teach a combination of benzyl alcohol and an aromatic carboxylic acid. The reference discloses aromatic carboxylic acid, but contains no specific combination of an aromatic acid and benzyl alcohol. The sole example using benzoic acid is free of benzyl alcohol, but rather contains a peracid as a second antimicrobial agent (Run 12-3).

The '422 publication also teaches the presence of a surfactant, with no apparent reason to exclude a surfactant, although some examples are surfactant free.

Taken as a whole, the rejection of the claims over the '422 publication fails for the same reason the claim rejections over the '186 patent fail. The '422 publication discloses individual components of the claimed invention, but not in the combination and amounts

recited in the claims that would have rendered the present method and composition obvious to a person skilled in the art.

When considering the claimed invention as a whole, a person skilled in the art would have had to make numerous jumps in reasoning to arrive at the presently claimed invention after reading the '422 publication with no apparent reason to do so. First, the benzyl alcohol would have to be selected from a wide list of solvents and would have to be used in the claimed amount (dipropylene glycol is not disclosed in the '422 publication), an aromatic carboxylic acid must be selected as the *sole* antimicrobial agent (although the '422 publication is directed to peracid antimicrobial agents), and a surfactant must be excluded from the formulation. The skilled artisan also would have to neglect the teachings of the '422 publication and exclude peracid compounds and diester dicarboxylates. The particularly claimed combination is neither taught nor suggested by the '422 publication, and the '422 publication fails to lead a skilled person to make these modifications. The '422 publication simply does not lead a person skilled in the art to such a conclusion, about hindsight reconstruction.

With respect to conducting experiments show unexpected results, as stated above, applicants have performed such supporting experiments, as set forth in the present examples.

In summary, for the reasons set forth above and with respect to the '186 patent, persons skilled in the art simply would not be motivated, or have any apparent reason, to make the several jumps in reasoning needed to arrive at the presently claimed invention after reading the '422 publication. Therefore, in view of the substantial differences between the '422 publication and the present claims, it is submitted that the rejection of the pending claims as being obvious over the '186 patent under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in proper form and scope for allowance. An early and favorable action on the merits is respectfully requested.



Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

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Respectfully submitted,

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